REMARKS

I respond to the Office Action mailed on December 20, 2006 and the references cited therewith.

Office Action mailed on December 20, 2006 was based on claims 1 to 20 that were originally on March 31, 2004. All claims were rejected. Claims have been amended so as to delete claim 10, which has now been merged with claim 1. Except for original claims 5, 9 and 12, all claims have been amended to meet the Learned Examiner's objections. Thus, claims 1- 19 are currently pending. Marked up copy of the claims and fresh clear copy of the claims are enclosed. Reconsideration and allowance of the currently amended claims is respectfully requested.

§112 Rejection of the Claims on the Ground of Lack of Enablement

Claims 1 to 20 were rejected under 35 U.S.C. § 112 for not reasonably providing enablement for preventing the transmission of most sexually transmitted. In light of the amendment to the claims, this objection is respectfully traversed.

Claim 1 have been amended so as to indicate that the composition of the present invention disinfects or inhibits or restrains or controls or reduces the potential transmission of *E. coli*, *Staphylococcus aureus*, *Hemolytic streptococcus*, *Pseudomonos aeruginosa*, *Candida albicans*, *Herpes Simplx virus II*, *Neisseria gonorrhea*, *Trichomanas vaginalis*, Hepatitis B virus, Hepatitis A virus, *Chlamydia trachomatis*, *Ureaplasma urealyticum*, *Treponema pallidum* or HIV. The language which is now adopted in claim 1 is based on the Examiner's own suggestion contained in paragraph 2 of page 3.

Additionally, I respectfully submit that working of the claimed composition has been tested under in-vitro conditions also. In this regard, I would like to submit a second declaration along with its enclosures which establishes that a number of tests have been conducted on animal models and on human beings to determine the working of the claimed composition.

In view of the amendment to the claims and the declaration which being submitted herewith, reconsideration and withdrawal of the rejection is respectfully requested.

§112 Rejection of the Claims on the Ground of Indefiniteness

Each of claims 2-4, 6-8, 13-15, 17-19 were rejected under 35 U.S.C. § 112 for indefiniteness. In light of the amendment to the claims, this objection is respectfully traversed.

I thank the Examiner for the close inspection of the claims and for his suggestion to delete the term "preferably" contained in each of claim 2-4, 6-8, 13-15 and 17-19. The claims have been amended as suggested by the learned Examiner and in view of the same, I respectfully request reconsideration and withdrawal of the rejection.

§103 Rejection of the Claims

Claims 1 to 20 were rejected under 35 U.S.C. § 103(a) as being allegedly un-patentable over Sackler et al. (4,954,351) in view of Thompson (5,308,611) in view of Davis et al (2004/0068218) in further view of Mody et al. (2003/0228376). This rejection is respectfully traversed.

To start with, I would like to submit that although the present application was filed with the USPTO on March 31, 2004, it claimed priority from Indian Patent Application No. which was filed on March 31, 2003. Hence, both Davis et al., and Mody et al., were not available on the date for reference by general public. In addition, as can be evidenced from the annexed second declaration, I had completed the invention in the year 1999 itself.

Nevertheless, I would respond to the objections contained in the office action on merits.

In this regard, I would like to bring to the kind attention of the learned Examiner that the composition of the present invention is a synergistic composition providing surprising results as set forth in the accompanying first Declaration. It is not possible to arrive at the presently claimed composition (which exhibits the surprising results), merely by reading Sackler et al., Thompson, Davis et al and Mody et al.

In the following paragraphs, a brief summary of the teachings of each of the cited document is provided:

US Patent No. 4,954,351 (hereafter shortly referred to as Sackler et al.):

The following statements which are contained in Sackler are quoted to start with:

Column 1, lines 34 to 41: "*For example, U. S Pat. No. 4,113,857 proposes a process for manufacturing iodophor preparations, in which it is stressed that the preparation should not contain any iodide ion, this being based on the recognition that the presence of iodide ion should be regarded as a contamination leading to a reduction of the free, elementary, caustic iodine.*"

Column 2, lines 20 to 24: "*From U. S Pat. No. 4,113,857iodophors such as PVP-iodine are known, in which iodide ions are considered disadvantageous. The aim is to produce iodide-free preparations which are not contaminated by iodide ions.*"

Thus, from the above statements, it can be concluded that presence of iodide ion along with PVP-I is undesirable. Thus, it can be said that both Sackler et al., and I have worked against the teachings of US Patent No. 4,113,857 in entirely different manner to achieve desired results.

Now coming to column 3, lines 9 to 21, it can be noticed that according to Sackler, the composition **mainly** comprises:

(a) polyvinyl pyrrolidone-iodine (PVPI);

(b) free iodine;

(c) a source of iodide ions; and

(d) a source of iodate ions (which is present as a source of oxidizing agent);

It can be noticed that according to Sackler, all the above-mentioned ingredients are essential constituents of the pharmaceutical iodophor preparation. **More particularly, according to Sackler et al., the pharmaceutical iodophor prepareation must contain the source of iodate ion**.

On comparison, the composition of the present invention only comprises:

(a) polyvinyl pyrrolidone-iodine (PVPI);

(b) a source of iodide ion;

the remaining two components i.e. source of free iodine and source of iodate are not present in the composition of the present invention.

The above described difference is in addition to the differences which have been acknowledged by the Examiner in the Office action i.e. (a) absence of chlorhexidine in the composition of Sackler et al. and (b) the difference in the ranges of all the ingredients.

Now considering the ranges of the ingredients present in the pharmaceutical iodophor preparation of Sackler et al, it can be noticed that in column 3, lines 9 to 21, it is provided that the preparation has a ratio of iodine to iodide between 2:1 and 10:1. In column 3, lines 22 and 23 it is given that the ratio of iodine to iodide is preferably between 2:1 and 6:1 and especially between 2:1 and 3.6:1.

On the other hand, by calculating the ratio of iodine to iodide in accordance with the currently pending claim 1, it can be noticed that the ratio of iodine to iodide is between 8:1 and 24:1.

At this stage, the following statements contained in Sackler et al. must be taken in to account:

(a) Column 2, lines 48 to 51: "*Of course, the level of free iodine must not become too high, otherwise the unwanted, side-effects of free iodine will apparent.*"

(b) Column 2, lines 52 to 54: "*it is the aim of the present invention to provide a povidone iodine preparation having a narrowly defined and stable level of free iodine.*"

Any person skilled in the art after reading these statements, would be believe that the composition would work only if the ratio of iodine to iodide is between 2:1 and 10:1 and not otherwise. As the ratio of iodine to iodide is on the higher side in the present application, a person skilled would be tempted to believe that the composition of the present invention would cause the un-wanted side-effects of free iodine. However, this is not the case, as can be seen from the multitude of certificates which have been issued in respect of the present composition, which is given the trade name of Genvia®.

US Patent No. 5,308,611 (hereafter shortly referred to as Thompson):

As can be noticed, Thompson teaches an antiseptic composition comprising Chlrohexidine acetate, citric acid, glycerin and Sodium lauryl sulphate. As the learned Examiner accepts, Thompson et al does not disclose a composition which contains polyvinyl pyrrolidone-iodine (PVPI), free iodine, a source of iodide ions and a source of iodate ions. Except for the use of citric acid, there is no common feature between the composition of Sackler et al., and the composition of Thompson. The teachings of Thompson are to be combined with the teachings of Sackler et al., merely because both the documents are teaching antiseptic composition.

It appears that any two documents could be combined merely because they are directed towards a common goal. More specifically, it appears that it is possible to combine two documents which are directed towards a common goal, but having gross differences in the routes adopted to achieve the goal. If the Law allows the Examiner to combine such two documents having gross differences in the concepts adopted to achieve a common goal, then the issue of "on what basis has the Examiner pulled out the two documents?" would arise. As the learned Examiner would be aware, there may be more than thousands of topical compositions available containing millions of active ingredients. The only way by which the learned Examiner could have pulled out two documents having such gross differences in the concepts and combine them to presumably destroy the invention would be by a hindsight reading of the claimed invention, which is not correct.

Even if we adopt the above mechanism of combining the documents, the learned Examiner would still notice that a composition flowing of such combination would comprise of Chlrohexidine acetate, citric acid, glycerin, Sodium lauryl sulphate, polyvinyl pyrrolidone-iodine (PVPI), free iodine, a source of iodide ions and a source of iodate ions. As the learned Examiner would notice, the composition being claimed in the presently pending claim is not what has been described above. More specifically, the claimed composition does not contain all the ingredients that are present in the above alleged composition.

In order to eliminate even a single ingredient and more specifically, even a single active ingredient, from the composition flowing of such combination, lot of experimentation has to be

conducted. Neither Sackler et al., or Thompson teaches that after combining their teachings, some ingredients should be or can be eliminated. Thus, all the metes and bounds of the composition claimed in claim 1 cannot be arrived even by combining the teachings of Sackler et al., and Thompson.

US Application Publication No. 2004/0068218 (hereafter referred to as Davis et al):

As observed by the learned Examiner, Paragraph 42 of the cited document Davis et al contains the following statements:

"*The containers used in connection with the present invention may be filled with a skin antiseptic composition that includes (as the antimicrobial agent) iodine, iodine complex, chlorihexidine, chlorihexidine salts, or combinations thereof. Preferred iodine complexes may include iodophors, e.g., povidione-iodine USP. Preferred chlorihexidine salts may include, e.g., chlorihexidine digluconate and chlorihexidine diacetate.*"

However, these are not only statements that are contained in paragraph 42. In addition to the above statements, paragraph 42 further states as under:

"*Other suitable antimicrobial agents may include C2-C5 lower alkyl alcohols (including, e.g., ethyl alcohol, 1-propanol, and 2-propanol), parachlorometaxylenol (PCMX), triclosan, hexachlorophene, fatty acid monoesters of glycerin and propylene glycol such as glycerol monolaurate, glycerol monocaprylate, glycerol monocaprate, propylene glycol monolaurate, propylene glycol monocaprylate, propylene glycol moncaprate, phenols, surfactants, and polymers that include a (C12-C22)hydrophobe and a quaternary ammonium group, polyquaternary amines such as polyhexamethylene biguanide, quaternary ammonium silanes, silver, silver salts (such as silver chloride), silver oxide and silver sulfadiazine, methyl, ethyl, propyl and butyl parabens, octenidene, peroxides (e.g., hydrogen peroxide and benzoyl peroxide), and the like, as well as combinations thereof.*"

Thus, it can be noticed that the above specification merely states "n" number of antimicrobial agents and leaves the gates open for the general public to work on the composition. If completely interpreted, the forty second paragraph, which the Examiner is relying upon, teaches nothing less than 1,000 antiseptic compositions. Once again the issue of what would prompt a person reading the document to choose a particular combination from the vast

alternatives is not clear. Simply put, such choice can be made only by hindsight reading of the claimed invention and not in any other manner, which is an incorrect way of rejecting an application.

Just for the sake of argument, even if we assume that a person skilled in the art comes up with a composition comprising PVP-I and chlorihexidine merely by reading paragraph 42 of Davis et al., and without performing any experimentation, still, there is no clue provided by Davis that such a combination would exhibit results superior to the results in respect of at least PVP-I and chlorihexidine taken individually. As indicated above, claim 1 is directed towards a synergistic composition, wherein the combination provides better results than the constituents taken individually.

Now if we combine the teachings of Davis et al., with the teachings of Sackler et al., taken along with Thompson, it would not be possible to come up with the composition claimed in claim 1. The composition that would be allegedly obtained by combining of Sackler et al., and Thompson (as already described above) would comprise of Chlrohexidine acetate, citric acid, glycerin, Sodium lauryl sulphate, polyvinyl pyrrolidone-iodine (PVPI), free iodine, a source of iodide ions and a source of iodate ions. As Davis et al., does not teach elimination of any ingredient from the above alleged composition, at least all the ingredients that are present in the alleged composition must be present, if not an additional ingredient.

Thus, the learned Examiner would notice, the composition being claimed in the presently pending claim is not what has been described above. More specifically, the claimed composition does not contain all the ingredients that are present in the above alleged composition which would be obtained by combining the teachings of Sackler et al., Thompson and Davis et al.

In order to eliminate even a single ingredient and more specifically, even a single active ingredient, from the composition flowing of such combination, lot of experimentation has to be conducted. Neither Sackler et al., or Thompson or Davis et al., teaches that after combining their teachings, some ingredients should be eliminated or can be eliminated. Thus, all the

metes and bounds of the composition claimed in claim 1 cannot be arrived even by combining the teachings of Sackler et al., and Thompson and Davis et al.

US Patent Publication No. 2003/0228376 (herein after referred to as Mody et al.):

As can be noticed, Mody et al., teaches a topical microbicidal composition which comprises metronidazole and PVP-Iodine. More particularly, Mody et al., teaches a composition for treatment of microbial infections comprising Povidone-Iodine, citric acid, Metronidazol, polyethylene glycol, sodium lauryl sulphate (surfactant) and Dibasic sodium phosphate.

As the learned Examiner would notice, mody et al does not disclose a composition which contains a source of free iodine, a source of iodide ions and a source of iodate ions. The teachings of Mody et al., are to be combined with the teachings of Sackler et al., Thompson and Davis et al., merely because all the documents are teaching antiseptic composition.

Even if we adopt the above mechanism of combining the documents as suggested by the learned Examiner, it can be noticed that the composition flowing of such combination would comprise of Chlrohexidine acetate, citric acid, glycerin, Sodium lauryl sulphate, polyvinyl pyrrolidone-iodine (PVPI), free iodine, a source of iodide ions, a source of iodate ions and metronidazole. As the learned Examiner would notice, the composition being claimed in the presently pending claim is not what has been described above. More specifically, the claimed composition does not contain all the ingredients that are present in the above alleged composition.

As described above, in order to eliminate even a single ingredient and more specifically, even a single active ingredient, from the above alleged composition, lot of experimentation has to be conducted. Neither Sackler et al., or Thompson or Davis et al., or mody et al., teaches that after combining their teachings, some ingredients from the composition should be or can be eliminated. Thus, all the metes and bounds of the composition claimed in claim 1 cannot be arrived even by combining the teachings of Sackler et al., Thompson, Davis et al., and Mody et al.

Summary

A prima facie case of obviousness cannot be maintained with respect to the rejections of amended claims 1 to 19. Applicant's claimed synergistic composition and the process for preparing the synergistic composition is novel that provides surprising result as outlined in the annexed Declaration. Sackler et al. (4,954,351) comprises ingredients, such as source of free iodine and source of iodate that are not present in the composition of the present invention. Furthermore, no teaching or suggestion has been identified that would lead the skilled artisan to combine the teachings of Sachler et al., Thompson (5,308,611), Davis et al (2004/0068218) and Mody et al. (2003/0228376) in a manner necessary to arrive at the Applicant's claimed invention. Acordingly, withdrawal of the rejection under 35 U.S.C. § 103 and allowance of the claims is respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is requested to telephone the Applicant at (404) 659-9900 to facilitate prosecution of this application.

Respectfully submitted,

Samuel C. Evans [redacted]

Date

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